

**IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY  
NEWARK DIVISION**

BARBARA A. BOYD,	)	
	)	CASE NO.:
Plaintiff,	)	
	)	
v.	)	
	)	
ASTRAZENECA PHARMACEUTICALS	)	
LP; and ASTRAZENECA LP,	)	
	)	<b>JURY TRIAL DEMANDED</b>
Defendants.	)	
	)	
	)	

**COMPLAINT**

Plaintiff, Barbara A. Boyd, for her Complaint alleges as follows:

**NATURE OF THE ACTION**

1. This is an action for personal injuries and economic damages suffered by Plaintiff Barbara A. Boyd (“Plaintiff”) as a direct and proximate result of the Defendants’ negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling and/or sale of the proton pump inhibiting drug (“PPI”) known as Nexium (esomeprazole magnesium) and/or other Nexium-branded products with the same active ingredient (herein collectively referred to as “Nexium”).
  
2. During the period in which Nexium has been sold in the United States, Defendants have had notice of serious adverse health outcomes through case reports, clinical studies and post-market surveillance. Specifically, Defendants had received numerous case reports of kidney injuries in patients that had ingested Nexium and other PPIs by as early as 2004.

3. Despite being on notice as to the excessive risks of kidney injuries related to the use of Nexium, Defendants took no action to inform Plaintiff or Plaintiff's physicians of this known risk. Rather, Defendants continued to represent that Nexium did not pose any risks of kidney injuries.

4. In omitting, concealing, and inadequately providing critical safety information regarding the use of Nexium in order to induce its purchase and use, Defendants engaged in and continue to engage in conduct likely to mislead consumers, including Plaintiff, resulting in the development of kidney injuries.

### **PARTIES**

#### **Plaintiff, Her use of Nexium and Resulting Harm**

5. At all times referenced herein, Plaintiff Barbara Boyd was and is a citizen of the State of South Carolina.

6. Plaintiff was born on January 26, 1941.

7. Plaintiff was prescribed Nexium on numerous occasions, including but not limited to, June 5, 2007 through September 22, 2011. Plaintiff Barbara Boyd ingested Nexium as prescribed by her doctor.

8. Plaintiff read and followed the directions regarding the use of Nexium and would not have used Nexium had she been properly appraised of the risks associated with the use of Nexium.

9. Plaintiff was diagnosed with Acute Interstitial Nephritis ("AIN") as early as September 22, 2011 while taking Nexium as prescribed.

10. Plaintiff has also suffered from acute renal failure while taking Nexium as prescribed.

**Defendants**

AstraZeneca Pharmaceuticals LP

11. Defendant AstraZeneca Pharmaceuticals LP is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.

12. At all times relevant hereto, Defendant AstraZeneca Pharmaceuticals LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Nexium products.

13. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP was present and doing business in Plaintiff's state of residency.

14. At all relevant times, Defendant AstraZeneca Pharmaceuticals LP transacted, solicited, and conducted business throughout the United States, including in Plaintiff's state of residency, and derived substantial revenue from such business.

15. At all times relevant hereto, Defendant AstraZeneca Pharmaceuticals LP expected or should have expected that its acts would have consequences within the United States of America, including in Plaintiff's state of residency.

16. Defendant AstraZeneca Pharmaceuticals LP is the holder of approved New Drug Applications ("NDAs") for the following forms of Nexium:

- a. Delayed-Release Capsule Pellets (20 mg and 40 mg) , with NDA # 021153, approved on 2/20/2001;
- b. Delayed-Release Oral Suspension Packets (2.5MG, 5MG, 20MG, 40MG), with NDA # 021957, approved on 10/20/2006;
- c. Delayed-Release Oral Suspension Packets (10MG), with NDA number 022101, approved on 02/27/2008; and

- d. Injection (20MG VIAL, 40MG VIAL), with NDA number 022101, approved on 03/31/2005.

AstraZeneca LP

17. At all times relevant hereto, Defendant AstraZeneca LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Nexium products.

18. Defendant AstraZeneca LP is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.

19. Upon information and belief, at all relevant times, Defendant AstraZeneca LP was present and doing business throughout the United States, including in Plaintiff's state of residency.

20. At all relevant times, Defendant AstraZeneca LP transacted, solicited, and conducted business throughout the United States, including in Plaintiff's state of residency, and derived substantial revenue from such business.

21. At all times relevant hereto, Defendant AstraZeneca LP expected or should have expected that its acts would have consequences within the United States, including in Plaintiff's state of residency.

AstraZeneca Pharmaceuticals LP & AstraZeneca LP's Unity of Interest

22. Defendants AstraZeneca LP and AstraZeneca Pharmaceuticals LP shall herein be collectively referred to as "Defendants" or "AstraZeneca."

23. Upon information and belief, at all relevant times, each of the Defendants and their directors and officers acted within the scope of their authority. During the relevant times, Defendants possessed a unity of interest between themselves and exercised control

over their respective subsidiaries and affiliates.

24. Moreover, each Defendant was the agent and employee of each other, and in doing the things alleged was acting within the course and scope of such agency and employment and with each other Defendant's actual and implied permission, consent, authorization, and approval. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiff for Plaintiff's injuries, losses and damages.

### **JURISDICTION AND VENUE**

25. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332(a)(1) because this case is a civil action where the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs, and is between citizens of different States.

26. Venue is properly set in this District pursuant to 28 U.S.C. §1391(b) because Defendants transact business within this judicial district. Likewise, a substantial part of the events giving rise to the claim occurred within this judicial district.

27. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, the Court has personal jurisdiction over Defendants, because Defendants are present in this District, such that requiring an appearance does not offend traditional notions of fair play and substantial justice. Further, Defendants have maintained registered agents in this District.

28. This court has personal jurisdiction over Defendants pursuant to and consistent with the Constitutional requirements of Due Process in that Defendants, acting through their agents or apparent agents, committed one or more of the following:

- a. The transaction of any business within the state;
- b. The making of any contract within the state;

- c. The commission of a tortious act within this state; and
- d. The ownership, use, or possession of any real estate situated within this state.

29. Requiring Defendants to litigate these claims in this District does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution. On information and belief, Defendants' Nexium products are sold at hundreds of local and national pharmacies, including, but not limited to Wal-Mart, Target, CVS, and Walgreens throughout this District.

30. On information and belief, Defendants avail themselves of numerous advertising and promotional materials regarding their defective Nexium products specifically intended to reach consumers throughout the United States, including, but not limited to, advertisements in this District on local television programs, advertisements on local radio broadcasts, advertisements on billboards in this District and advertisements in print publications delivered to consumers in this District.

31. Defendants regularly conduct or solicit business and derive substantial revenue from goods used or consumed in, *inter alia*, this District.

32. Upon information and belief, at all relevant times, Defendant AstraZeneca LP was present and doing business in this District.

33. At all relevant times, Defendant AstraZeneca LP transacted, solicited, and conducted business in this District and derived substantial revenue from such business.

34. At all times relevant hereto, Defendant AstraZeneca LP expected or should have expected that its acts would have consequences within the United States of America, including in this District.

35. At all relevant times, Defendants placed Nexium products ingested by Plaintiff into the stream of interstate commerce.

36. At all relevant times, Defendants expected or should have expected that their acts and omissions would have consequences within the United States, including in this District.

### **FACTUAL BACKGROUND**

#### **Proton Pump Inhibitors Generally**

37. Proton pump inhibitors (“PPI”) are one of the most commonly prescribed medications in the United States to treat conditions such as:

- a. Gastroesophageal reflux disease (GERD)
- b. Dyspepsia
- c. Acid peptic disease
- d. Zollinger-Ellison syndrome
- e. Acid reflux, and
- f. Peptic or stomach ulcers.

38. In 2013, more than 15 million Americans used prescription PPIs, costing more than \$10 billion. Of these prescriptions, however, it has been estimated that between 25% and 70% of them have no appropriate indication.

39. AstraZeneca sold Nexium with National Drug Code (NDC) numbers 0186-5020, 0186-5022, 0186-5040, 0186-5042, 0186-40100186-4020, and 0186-4040.

40. Nexium is AstraZeneca’s largest-selling drug and, in the world market, the third largest selling drug overall. In 2005, AstraZeneca’s sales of Nexium exceeded \$5.7 billion dollars. In 2008, Nexium sales exceeded \$5.2 billion dollars.

41. Nexium (esomeprazole magnesium) is a PPI that works by inhibiting the secretion of stomach acid. It shuts down acid production of the active acid pumps in the stomach, reducing hydrochloric acid in the stomach. The drug binds with the proton pump which inhibits the ability of the gastric parietal cell to secrete gastric acid.

**Dangers Associated with PPIs**

42. Even if used as directed, Defendants failed to adequately warn against the negative effects and risks associated with this product including, but not necessarily limited to, long term usage and the cumulative effects of long term usage.

43. During the period in which Nexium has been sold in the United States, hundreds of reports of injury have been submitted to the FDA in association with ingestion of Nexium and other PPIs. Defendants have had notice of serious adverse health outcomes through case reports, clinical studies and post-market surveillance. Specifically, Defendants have received numerous case reports of several types of kidney and related injuries in patients that had ingested Nexium, including but not limited to:

- a. Acute Interstitial Nephritis (AIN),
- b. Chronic Kidney Disease (CKD),
- c. Renal/Kidney Failure,
- d. Acute Kidney Injury (AKI), and
- e. Clostridium difficile.

44. These reports of numerous injuries put Defendants on notice as to the excessive risks of injuries related to the use of Nexium. However, Defendants took no action to inform Plaintiff or Plaintiff's physicians of this known risk. Instead, Defendants continued to represent that Nexium did not pose any risks of kidney injuries.

**Increased Risk of Acute Interstitial Nephritis (AIN) with PPIs**

45. Acute Interstitial Nephritis (AIN) is the inflammation of the tubes and tissues of the kidneys. The most common symptoms are fatigue, nausea and weakness. AIN-related symptoms can begin as early as one week following PPI ingestion.

46. The risk of AIN among PPI users was first raised in 1992. Five years later, an additional study raised concerns. By 2011, the World Health organization adverse drug reaction



report included nearly 500 cases of AIN.

47. Between 2004 and 2007, at least three additional studies confirmed AIN related to PPI usage. More recent studies indicate that those using PPIs such as Nexium are at a three times greater risk than the general population to suffer AIN.

48. On or about October 30, 2014, the FDA notified Defendants that the FDA determined that PPIs (and all forms for Nexium, specifically) pose additional risks not previously disclosed. *See* FDA Letter, dated December 19, 2014, to Laura Garcia-Davenport, Director of Regulatory Affairs at AstraZeneca Pharmaceuticals (“We also refer to our letter dated October 30, 2014, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Nexium.”), available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2014/021153Orig1s050,021957Orig1s017,022101Orig1s014ltr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/021153Orig1s050,021957Orig1s017,022101Orig1s014ltr.pdf).

49. In December 2014, the labeling for PPIs was updated to include a warning about Acute Interstitial Nephritis (AIN). *See* December 2014 revised label, available at <http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm290945.htm>.

50. Various medical studies and journals support the fact that there is an association between PPIs, including Nexium, and AIN. *See, e.g.,* Blank M-L, Parkin L, Paul C, et al., *A nationwide nested case-control study indicates an increased risk of acute interstitial nephritis with proton pump inhibitor use*, *Kidney Int'l* (Published online Mar. 19, 2014); 86:837–44; available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4184187/>. *See also* *Proton Pump Inhibitors: When is enough, enough?*, *Best Practice Journal*, Issue 61 (June 2014), available at <http://www.bpac.org.nz/BPJ/2014/June/ppi.aspx>, updated in *Proton Pump Inhibitors and the risk of acute kidney injury*, *Best Practice Journal*, Issue 76 (July 2016), available at

<http://www.bpac.org.nz/BPJ/2016/July/update.aspx>.

51. Even the current warning of AIN is far from complete, lacking the necessary force to give patients and treating physicians the proper information needed to make an informed decision about whether to start a drug regimen with such potential dire consequences.

52. If left untreated, AIN can lead to Chronic Kidney Disease (CKD) and kidney failure.

**Association between Chronic Kidney Disease (CKD) and PPIs**

53. CKD is the gradual loss of kidney function. Kidneys filter wastes and excess fluids from the blood, which are then excreted. When chronic kidney disease reaches an advanced stage, dangerous levels of fluid, electrolytes and wastes can build up in the body.

54. In the early stages of CKD, patients may have few signs or symptoms. CKD may not become apparent until kidney function is significantly impaired.

55. Treatment for CKD focuses on slowing the progression of the kidney damage, usually by attempting to control the underlying cause. CKD can progress to end-stage kidney failure, which is fatal without artificial filtering, dialysis or a kidney transplant. Early treatment is often key to avoiding the most negative outcomes.

56. CKD is associated with a substantially increased risk of death and cardiovascular events.

57. Studies have shown the *long term* use of PPIs was independently associated with a 20% to 50% higher risk of CKD, after adjusting for several potential confounding variables, including demographics, socioeconomic status, clinical measurements, prevalent comorbidities, and concomitant use of medications.

58. In at least one study, the use of PPIs for *any period of time* was shown to

increase the risk of CKD by 10%.

59. As a whole, patients with renal disease are nearly twice as likely to have been exposed to PPIs compared to those without renal disease.

60. Various medical studies support the fact that there is an association between PPIs, including Nexium, and CKD. *See, e.g., JAMA Intern Med.* 2016; 176(2): pp. 238-246, “Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease,” Published online January 11, 2016, Corrected on February 29, 2016.

61. Currently, Nexium lacks any warning of CKD.

**Acute Kidney Injury (AKI) Dangers Associated with PPIs**

62. Studies indicate that patients taking PPIs, such as Nexium, are at greater than a 2.5 times greater risk than the general population to suffer AKI.

63. Studies also indicate that those who develop AIN are at a significant risk of developing AKI even though there may not be obvious case kidney dysfunction.

64. Various medical studies support the fact that there is an association between PPIs, including Nexium, and AKI. *See, e.g.,* Klepser DG, Collier DS, Cochran GL. *Proton pump inhibitors and acute kidney injury: a nested case-control study*, BMC Nephrol 2013; 14:150; available at <http://bmcnephrol.biomedcentral.com/articles/10.1186/1471-2369-14-150>; Antoniou T, Macdonald EM, Hollands S, et al. *Proton pump inhibitors and the risk of acute kidney injury in older patients: a population-based cohort study*. CMAJ 2015;3: E166–71; available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4571830/>.

65. Currently, Nexium lacks any warning of AKI.

**Availability of Safer Alternatives to PPIs**

66. Despite the fact that Nexium and other PPIs lead to an increased risk of

the injuries outlined herein, numerous safer alternatives are available.

67. Such safer alternative treatments include but are not limited to:

- a. the use of over-the-counter calcium carbonate remedies tablets, such as Maalox and Tums, that have been available since the 1930s, and/or
- b. the use of histamine H<sub>2</sub>-receptor antagonists (also known as H<sub>2</sub> blockers) that were developed in the late 1960s. H<sub>2</sub> blockers act to prevent the production of stomach acid, and work more quickly than PPI.

Examples of H<sub>2</sub> blockers are Zantac, Pepcid, and Tagamet.

68. Even though these safer alternatives at all relevant times existed, the sale of PPIs such as Nexium skyrocketed at the same time that the safer alternatives, namely the H<sub>2</sub> blockers, plummeted.

69. This is true despite the fact that higher kidney injury risks are specific to PPI medications. The use of H<sub>2</sub> receptor antagonists, which are prescribed for the same indication as PPIs, is not associated with such renal injuries.

#### **Allegations Common to All Causes of Action**

70. Defendants knew or should have known about the correlation between the use of Nexium and the significantly increased risk of AIN, CKD, AKI, and renal impairment. Yet Defendants failed to adequately warn against these negative effects and risks associated with Nexium.

71. In omitting, concealing, and inadequately providing critical safety information regarding the use of Nexium to Plaintiff and Plaintiff's doctors in order to induce its purchase, prescription and use, Defendants engaged in and continue to engage in conduct likely to mislead consumers including Plaintiff and Plaintiff's doctors. This conduct is fraudulent,

unfair, and unlawful.

72. Despite clear knowledge that Nexium causes a significantly increased risk of AIN, CKD, AKI, and renal impairment, Defendants continue to market and sell Nexium without warning consumers or healthcare providers of these significant risks.

### **TOLLING OF THE STATUTE OF LIMITATIONS**

73. Defendants, at all relevant times, knew or should have known of the problems and defects with Nexium products, and the falsity and misleading nature of Defendants' statements, representations and warranties with respect to Nexium products. Defendants concealed and failed to notify Plaintiff and the public of such defects.

74. Any applicable statute of limitation has therefore been tolled by Defendants' knowledge, active concealment and denial of the facts alleged herein, which behavior is ongoing.

### **CASE- SPECIFIC INFORMATION**

75. Upon information and belief, on approximately June 8, 2007, Shari Carter, FNP discussed prescribing Nexium to Plaintiff. Ms. Carter discussed the risks and benefits of Nexium. Because Defendants did not disclose the true risks of acute and chronic kidney injuries associated with the use of Nexium to Ms. Carter, nor did Defendants disclose the true risks of acute and chronic kidney injuries in the information given to Plaintiff, it was impossible for Ms. Carter to adequately discuss the true risks and benefits of Nexium with Plaintiff. Consequently, it was impossible for Plaintiff to learn of the true risks associated with Nexium.

76. Plaintiff, after a consultation with Ms. Carter, began using Nexium on or about June 8, 2007. The Nexium used by Plaintiff remained in substantially the same condition between when it left Defendants' control and used by Plaintiff. Ms. Carter would not have

prescribed Nexium to Plaintiff if Ms. Carter knew of the true risks associated with the use of Nexium. In other words, Ms. Carter would not have prescribed Nexium to Plaintiff if she knew the true risks associated with the use of Nexium.

77. Plaintiff would not have elected to use Nexium if she knew of the true risks associated with the use of Nexium. In other words, Plaintiff would not have elected to use Nexium if she knew the true risk of acute and chronic kidney injuries associated with the use of Nexium.

78. Upon information and belief, on September 22, 2011, Plaintiff suffered Acute Interstitial Nephritis (“AIN”) and was hospitalized. Plaintiff suffered AIN because Nexium was negligently and defectively designed. Defendants knew that Nexium was negligently and defectively designed when it left Defendants’ control, and Defendants knew that it caused AIN at a higher rate than other similar medications on the market. Defendants did not disclose these facts to Ms. Carter or Plaintiff.

79. Through no fault of her own, and no fault of her health care providers, on September 22, 2011, Plaintiff suffered AIN. The AIN caused pain and suffering, financial loss and caused permanent injury to Plaintiff.

## **CAUSES OF ACTION**

### **COUNT I** **NEGLIGENCE**

80. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though set forth fully herein and further alleges as follows.

81. Defendants had a duty to exercise reasonable and ordinary care in the design, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions, and distribution of Nexium into the stream of commerce, including a duty to assure that its

product did not pose an undue risk of bodily harm and adverse events, and to properly warn of all risks, and comply with federal requirements.

82. Defendants failed to exercise reasonable and ordinary care in the design, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Nexium into the stream of commerce in that Defendants knew or should have known that the product caused significant bodily harm and was not safe for use by consumers. Specifically, Defendants failed to properly and thoroughly:

- a. Test Nexium before releasing it into the market;
- b. Analyze the data resulting from the pre-marketing tests of Nexium;
- c. Conduct sufficient post-market testing and surveillance of Nexium; and
- d. Provide appropriate warnings for consumers and healthcare providers including disclosure of the known or potential risks or true or suspected rates of serious kidney injury that may be irreversible, permanently disabling, and life-threatening.

83. Despite the fact that Defendants knew or should have known that their product posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market Nexium for use by consumers and continued to fail to comply with federal requirements.

84. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

85. It was foreseeable that Defendants' product, as designed, would cause serious injury to consumers, including Plaintiff.

86. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

87. Defendants' conduct as described above, including but not limited to their failure to adequately design, test, and manufacture, as well as its continued marketing and distribution of the Nexium when they knew or should have known of the serious health risks it created and the failure to comply with federal requirements, are evidence of a flagrant disregard of human life so as to warrant the imposition of punitive damages.

88. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, and willful and wonton conduct, which warrants the imposition of punitive damages.

WHEREFORE, Plaintiff respectfully requests an award of compensatory damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT II**  
**BREACH OF EXPRESS WARRANTY**

89. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though set forth fully herein and further alleges as follows.

90. Defendants expressly warranted that Nexium was a safe and effective product to be used as a proton pump inhibitor, and did not disclose the material risks that Nexium could cause serious kidney injury that may be irreversible, permanently disabling, and life-threatening. The representations were not justified by the performance of Nexium.

91. Members of the consuming public, including consumers such as Plaintiff, and her healthcare providers, were intended third party beneficiaries of the warranty.

92. Plaintiff and her healthcare providers reasonably relied on these express representations.



93. The Nexium manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to the Plaintiff when used as recommended and directed, and these risks were not disclosed to Plaintiff or her healthcare providers.

94. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff respectfully requests an award of compensatory damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT III**  
**BREACH OF IMPLIED WARRANTY**

95. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though set forth fully herein and further alleges as follows.

96. When Defendants designed, manufactured, marketed, sold, and distributed Nexium for use by the Plaintiff, Defendants knew of the use for which it was intended and impliedly warranted the product to be of merchantable quality and safe for such use and that its design, manufacture, labeling, and marketing complied with all applicable federal requirements.

97. Plaintiff and her physicians reasonably relied upon the Defendants' representations of the product's merchantable quality and that it was safe for its intended use, and upon Defendants' implied warranty, including that it was in compliance with all federal requirements.

98. Contrary to such implied warranty, Nexium was not of merchantable quality or safe for its intended use, because the product was defective, as described herein, and it failed to comply with federal requirements.

99. As a direct and proximate result of Defendants' breach of warranty, the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff respectfully requests an award of compensatory damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT IV**  
**FRAUD**

100. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though set forth fully herein and further alleges as follows.

101. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed Nexium, and up to the present, willfully deceived Plaintiff by concealing from her, her physicians and the general public, the true facts concerning Nexium, which the Defendants had a duty to disclose.

102. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of Nexium and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using Nexium. Defendants knew of the foregoing, that Nexium is not safe, fit and effective for human consumption, that using Nexium is hazardous to health, and that Nexium has a propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff suffered.

103. Defendants concealed and suppressed the true facts concerning Nexium with the intent to defraud Plaintiff, in that Defendants knew that Plaintiff's physicians would not prescribe Nexium, and Plaintiff would not have used Nexium, if they were aware of the true facts concerning its dangers.

104. As a result of Defendants' fraudulent and deceitful conduct, Plaintiff suffered injuries and damages as alleged herein.

WHEREFORE, Plaintiff respectfully requests an award of compensatory damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

**COUNT V**  
**NEGLIGENT MISREPRESENTATION**

105. Plaintiff incorporates by reference herein each of the allegations set forth in this Complaint as though fully set forth herein and further allege as follows.

106. From the time Nexium was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that Nexium was safe, fit and effective for human use. At all times mentioned, Defendants conducted sales and marketing campaigns to promote the sale of Nexium and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of Nexium.

107. The Defendants made the foregoing representation without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and

other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

108. The representations by the Defendants were in fact false, in that Nexium is not safe, fit and effective for human consumption, using Nexium is hazardous to health, and Nexium has a propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

109. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of Nexium.

110. In reliance of the misrepresentations by the Defendants, and each of them, Plaintiff was induced to purchase and use Nexium. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used Nexium. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

111. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered injuries and damages as alleged herein.

WHEREFORE, Plaintiff respectfully requests an award of compensatory damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

#### **PUNITIVE DAMAGES ALLEGATIONS**

112. Plaintiff incorporates by reference each of the allegations set forth in this Complaint as though set forth fully herein and further alleges as follows.

113. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights of Plaintiff and other Nexium users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Nexium. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

114. Prior to the manufacturing, sale, and distribution of Nexium, Defendants knew that Nexium was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using Nexium.

115. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Nexium and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Nexium. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Nexium knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

116. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with

willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

WHEREFORE, Plaintiff respectfully requests an award of punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

**RELIEF REQUESTED**

WHEREFORE, Plaintiff prays for judgment against all Defendants and award additional relief as follows:

1. Economic and non-economic damages, special damages and general damages, including pain and suffering, in an amount to be supported by the evidence at trial;
2. For compensatory damages for the acts complained of herein in an amount to be determined by a jury;
3. For disgorgement of profits for the acts complained of herein in an amount to be determined by a jury;
4. Punitive damages for the acts complained of herein in an amount to be determined by a jury;
5. For an award of attorneys' fees and costs;
6. For prejudgment interest;
7. For the costs of suit;
8. For post-judgment interest; and
9. For such other and further relief as this Court may deem just and proper.

**JURY TRIAL DEMAND**

Plaintiff demands a jury trial as to all claims and issues triable of right by a jury.

Respectfully submitted,

Dated: November 1, 2016

/s/ Dianne M. Nast  
NASTLAW LLC  
Dianne M. Nast  
Daniel N. Gallucci  
Joanne E. Matusko  
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